

Michigan Department of Health and Human Services (MDHHS)

Michigan Drug Assistance Program (MIDAP)

Prior Authorization Criteria for Hepatitis C Treatment

The patient must meet the following criteria for treatment of Hepatitis C:

1. Must be enrolled in the Michigan Drug Assistance Program prior to treatment start date
2. Must be co-infected with HIV
3. Is not eligible for treatment coverage through their insurance provider or is uninsured
4. Is chronically infected with HCV and have an HCV RNA positive test within 3 months of the treatment start date
5. Must be 18 years of age or older
6. Must be on HIV antiretroviral medications, controlled or virally suppressed (less than 200 copies) AND adherent
7. Documentation of the patients use or abuse of IV drugs and/or alcohol must be noted (patient must be screened and counseled about drug and/or alcohol use or abuse before and during treatment duration)
8. Drug-drug interactions have been identified and properly managed prior to HCV treatment
9. Documentation of the following must be provided on the Prior Authorization request:
 - a. HCV genotype (one-time genotype for initial request unless there is a recurrent or renewal request, then it must be repeated)
 - b. Detectable HCV RNA viral load (within the last 3 months)
 - c. ALT/AST (within the last 3 months)
 - d. CBC (within the last 3 months)
 - e. GFR (within the last 3 months)
 - f. Hepatitis A and B Serology
10. Metavir fibrosis score will be used to prioritize treatment access by MIDAP as documented by **one of the following (documentation must be submitted):**
 - a. Serum marker supporting a level of fibrosis of F2-F4 [APRI \geq 0.5, FIB-4 \geq 1.45, Fibrotest/Fibrosure \geq 0.48 (scores must be calculated where appropriate with supporting labs submitted)] or
 - b. Fibroscan \geq 7.0 kPa or
 - c. Fibrospect \geq 42
 - d. Shear Wave Velocity \geq 1.34 meters/second or
 - e. Liver biopsy demonstrating F2, F3, F4 or cirrhosis

Criteria for Denial of Hepatitis C Treatment

1. Patient is not abstaining from the use of illicit drugs and alcohol as evidenced by submitted blood and/urine confirmation test results
2. Diagnostic/disease severity evidence is not submitted with the request
3. HCV RNA results not submitted with the request
4. Treatment is not being managed by a Gastroenterologist, Hepatologist or Infectious Disease Specialist or no supporting documentation or supporting evidence of collaboration/consultation with the specialist has been submitted.
5. Patient is taking a concomitant medication that has a significant clinical interaction or is contraindicated with any of the agents
6. The patient has any disease or shortened life expectancy that cannot be remediate by Hepatitis C treatment that may limit their life span within 18 months
7. If the allocated number of treatment slots are full in each year, the Michigan Drug Assistance Program may defer the patient to the following year.